

# CERTIFICATE OF MAILING

I hereby certify that this paper, together with all enclosures identified herein, are being deposited with the United States Postal Service as first class mail, addressed to the Assistant Commissioner for Patents, Washington D.C. 20231, on the date indicated below.

November 11, 2003

Date

Melanie S. Jernberg

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Gary W. Cleary et al.

Appln. No.

10/625,327

Filing Date

July 23, 2003

For

ULTRA THIN FILM TRANSDERMAL/DERMAL OR

TRANSMUCOSAL/MUCOSAL DELIVERY SYSTEM

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97(b)

Pursuant to 37 CFR §§1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached Form PTO-1449. This Information Disclosure Statement is being filed more than three months after the filing date of the above-referenced application but, to the undersigned's knowledge, before the mailing date of a first Office Action on the merits for the above-referenced application.

Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

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Applicants wish to bring to the attention of the Patent Office the fact that as a result of cooperative activity, the subject matter of this patent application is disclosed in part in a patent application filed by Agile Therapeutics, Inc. on July 17, 2003. It will not be prior art, as the relevant subject matter was invented by the present Applicants.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 16-2463.

Respectfully submitted,

GARY W. CLEARY ET AL.

By: Price, Heneveld, Cooper, DeWitt & Litton

Movember 1, 2003

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# FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE ATTY. DOCKET NO. SERIAL NO. 10/625,327 (Rev. 2-32) PATENT AND TRADEMARK OFFICE COR21 P-304 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) APPLICANT Gary W. Cleary et al. **FILING DATE GROUP** July 23, 2003

### **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DO	CUM	ENT	NUM	BER		DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPRO- PRIATE
	6	0	4	3	4	0	6	03/28/2000	Sessions et al.			
J	5	9	5	1	5	0	5	09/14/1999	Gilman et al.			
	5	7	3	8	6	4	2	04/14/1998	Heinecke et al.		<del>-</del>	
	5	7	2	2	9	4	3	03/03/1998	Sessions			
	5	5	9	9	2	8	9	02/04/1997	Castellana			
	5	5	3	1	8	5	5	07/02/1996	Heinecke et al.			
	5	5	2	0	6	2	9	05/28/1996	Heinecke et al.			
	5	3	3	6	1	6	2	08/09/1994	Ota et al.			
	5	1	6	0	3	1	5	11/03/1992	Heinecke et al.			
,	5	0	8	8	4	8	3	02/18/1992	Heinecke			

# FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		D	OCUN	MENT	NUMB	ER	DATE	C	OUNTRY	CLASS	SUB- CLASS		NSLA- ION
												Y	N

# OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER INITIAL	
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EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

# FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Rev. 2-32) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO. COR21 P-304	SERIAL NO. 10/625,327
APPLICANT	

**GROUP** 

# U.S. PATENT DOCUMENTS

FILING DATE July 23, 2003

EXAMINER INITIAL		DOC	CUME	ENT N	NUME	BER		DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPRO- PRIATE
	R	Е	3	3	7	2	7	10/29/1991	Sims			
	5	0	0	0	1	7	2	03/19/1991	Ward			
	R	E	3	3	3	5	3	09/25/1990	Heinecke			
	4	9	1	7	9	2	9	04/17/1990	Heinecke			
	4	9	1	7	1	1	2	04/17/1990	Kalt			
	4	8	8	4	5	6	3	12/05/1989	Sessions			
	4	8	7	5	4	7	3	10/24/1989	Alvarez			
	4	7	5	3	2	3	2	06/28/1988	Ward			
	4	6	1	4	1	8	3	09/30/1986	McCracken et al.	<u> </u>		
	4	6	0	0	0	0	1	07/15/1986	Gilman	<u> </u>		

# FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER								COUNTRY	CLASS	SUB- CLASS	TRANSLA- TION

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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	4	5	9	8	0	0	4	07/04/1986	Heinecke			
	4	4	8	5	8	0	9	12/04/1984	Dellas			
•	4	3	7	2	3	0	3	02/08/1983	Grossmann et al.		-	
	4	8	1	6	2	5	8	03/28/1989	Nedberge et al.			
	4	9	9	7	6	5	5	03/05/1991	Nagy et al.			
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# FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		D	OCUN	MENT I	NUMBI	ER	DATE	COUNTRY	CLASS	SUB- CLASS	1	NSLA- ION
			-				 				Y	N

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